## REMARKS

The Official Action dated August 9, 2004, has once more repeated the rejections of claims 1 to 18 and 32 to 35 that were first set forth in the Official Action dated November 30, 2004. Applicants respectfully maintain their traverse of these rejections. The previously submitted arguments and reasoning in support of the patentability of the claims are neither withdrawn nor abandoned.

Briefly, however, claim 1 is not obvious over Cook in view of Fowler and further in view of Campbell. The Cook and Fowler references are improperly combined, because the basic principles under which the Cook and Fowler constructions were designed to operate are not the same.

Specifically, the Cook fabric consists of a network of yarns with interlacing segments in both the longitudinal and circumferential directions [Figure 4], which are comprised of colinear hard and elastic components. This fabric expands in both the longitudinal and circumferential directions to accommodate stresses in those directions generated by the balloon inflation. Moreover, when the pressure is released, the Cook fabric will contract in both directions due to the elastic component in the constituent yarns in both directions.

In contrast, the Fowler fabric consists of a network of elastic yarns in one direction and hard yarns in the other, it will expand only in the direction of the elastic yarns (as the internal bladder is filled). As contents of the contained bladder are released, the fabric will contract in the desired unidirectional fashion.

These are two completely different principles of operation. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103 citing Cook in view of Fowler and further in view of Campbell be withdrawn upon reconsideration.

Claims 2 through 18 and 32 through 35 depend, directly or indirectly, from claim 1. Moreover, the rejection of each of these claims is based, at least in part, on the Cook, Fowler, and Campbell references. It follows by logic and by statute that these claims are also patentable, for at least the same reasons that claim 1 is patentable. Therefore, Applicants respectfully request that the rejection of claims 2 through 18 and 32 through 35 under 35 U.S.C. § 103 be withdrawn upon reconsideration

Claims 36 to 38, which depend from claim 1, have also been rejected under 35 U.S.C. § 103 as obvious over Cook in view of Fowler and further in view of Campbell. As noted above, it follows by statute that dependent claims 36 to 38 are not obvious over the cited references, for at least the same reasons that independent claim 1 is not obvious. Accordingly, Applicants respectfully request that the rejection of claims 36 to 38 citing Cook, Fowler, and Campbell also be withdrawn upon reconsideration.

Also in response to the Official Action dated August 9, 2005, Applicants respectfully take issue with several points that have been newly raised in that document. For example, Applicants have taken great care to avoid speculation and to identify, with particularity, support in the specification and in the cited references for the propositions that are set forth in the responses of record. This same care was exercised in the preparation of the response filed on June 24, 2005. Nevertheless, Applicants are accused of submitting speculative or unsupported assertions. See paragraph 9 of the Official Action.

The facts marshalled to support this accusation seem rather to suggest that Applicants are guilty of arguing from the converse. Applicants respectfully submit, however, that they have entered no arguments from the converse into the record. Rather, the more abstract statements in the cited references, on which the Official Action relies, may not characterize the prior art catheter covers

accurately or completely. This is why Applicants have based their reasoning on the specific descriptions of yarn properties and fabric construction that are set forth in Cook and Fowler. It is believed that some predictions of the mechanical behavior of the catheter covers may be made with a degree of certainty based on the yarns' properties and connectivity.

In addition to the arguments and reasoning presented herein and previously in the prosecution of the present application, the Examiner's attention is respectfully directed to the following secondary considerations. Specifically, the balloon catheter covers of the invention fulfill a long felt but unmet need, and they perform successfully in ways that others have failed.

In this connection, it is respectfully requested that judicial notice be taken of a manufacturer's recall of certain coronary stent systems. See, for example, the recall notice dated July 1, 2004, and published on the Food and Drug Administration's (FDA's) web site (http://www.fda.gov/cdrh/recalls/recall-070104.html; accessed on February 9, 2006). The life-threatening danger caused by these stents is clearly stated:

> Use: The [Boston Scientific] stent system consists of a stent (small metal tube) which is mounted on a balloon catheter. The stent is inserted into a blood vessel and advanced within the vessel to the narrowed section of the coronary artery. When the stent is correctly positioned, the balloon is inflated, causing the stent to expand. Expansion of the stent pushes the plaque aside, opening the narrowed section of the artery restoring normal blow flow to the heart. The balloon on the stent delivery catheter is then deflated and the delivery catheter is removed from the patient. The stent remains permanently implanted supporting the newly opened section of the vessel...
>
> ...
>
> **Reason for Recall: Characteristics in the design of these two lots resulted in failure of the balloon to deflate** and impeded removal of the balloon after stent placement. [*Emphasis supplied.*]

Moreover, the problem was ongoing in the year after the recall was promulgated, as is demonstrated by the following publication:

> Report: Boston Scientific stents had problems after recall
> By Associated Press
> Wednesday, July 13, 2005 - Updated: 10:36 AM EST
>
> NEW YORK - Boston Scientific reportedly continues to have the same problems with some of its cardiac stents that led to a temporary recall last year. The Wall Street Journal reports that doctors are still reporting injuries during the implantation of the stents.
>
> The stents are small, wire-mesh tubes inserted into clogged arteries to open them up. The problem, according to Food and Drug Administration records, is that **balloons used to deploy the stents failed to deflate** or were so hard to remove that three people died and dozens more were injured during operations performed after the recalls.
>
> The Journal says that a review of the FDA data shows that between last October and April of this year, the agency received at least 45 reports of deflation difficulties with Natick-based Boston Scientific stent balloons. In 86 other cases, doctors reported that the balloons became stuck or otherwise were difficult to withdraw from a patient's body. [*Emphasis supplied.*]

Ample evidence is presented, however, in the specification and in the prosecution history to date, to demonstrate that the balloon catheter cover of the invention deflates rapidly and uniformly. See, for example, page 6 at lines 3 to 20, and, in particular, the test results for Example 3 that are set forth on pages 23 and 24, and in the accompanying Figures. Specifically, the balloon catheters balloon catheter equipped with a balloon catheter cover of the invention were bicompliant and self folding upon the release of pressure. Moreover, the data in Figure 12 show that, within 400 milliseconds after the release of pressure, the balloon catheters had collapsed completely. Thus, the balloon catheter cover of the invention fulfills a long felt but unmet need and overcomes the failure of others.

In summary, Applicants do not believe that a *prima facie* case of the obviousness of the present invention can be made out over Cook, Fowler and Campbell. In the alternative, however, Applicants respectfully submit that the evidence of secondary considerations presented herein and in the specification is sufficient to overcome a *prima facie* case of obviousness over the cited references. Consequently, Applicants respectfully request that the rejection of claims 1 to 18 and 32 to 38 under 35 U.S.C. § 103 be withdrawn upon reconsideration.

Conclusion

A Petition for an Extension of Time for three months and the required fee for the extension is filed concurrently herewith. Should any further fee be required in connection with the present amendment, the Examiner is authorized to charge such fee to Deposit Account No. 04-1928 (E.I. du Pont de Nemours and Company).

In view of the above remarks, it is felt that all claims are in condition for allowance and such action is respectfully requested. Should the Examiner believe that an interview or other action in Applicants' behalf would expedite prosecution of the application, the Examiner is urged to contact Applicants' attorney by telephone at (302) 892-1004.

Respectfully submitted,

Maria M. Kourtakis

**MARIA M. KOURTAKIS**
ATTORNEY FOR APPLICANTS
Kelly Law Registry on behalf of DuPont Legal
Registration No. 41,126
Telephone: (302) 892-1004
Facsimile: (302) 992-3257

Dated: February 9, 2006